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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,949	05/01/2002	Guy Couaraze	03715.0105	8770

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/031,949	COUARAZE ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Nathan Schlientz can be reached at 571-272-9924.

Specification Objection

The objection with respect to the specification is hereby withdrawn by the examiner.

Claim Rejections - 35 USC § 112, First Paragraph

The rejection of Claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby withdrawn by the examiner, because after further consideration, the statement on page 10, lines 35-37, is merely a preferred embodiment and not a definition for neutral microgranules.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 1 and 3-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states, "the neutral microgranules are essentially spherical granules ***comprising*** between 62.5 and 91.5% of sucrose, the remainder being ***composed essentially of*** starch...". The term "comprising" is an open-ended limitation that affords additional ingredients other than sucrose. However,

the term "composed essentially of" is limited to only additional ingredients that are not essential to the function of the microgranule. The use of comprising and consisting essentially of lends confusion to the claimed limitation. For instance, the claim may be interpreted in two different manners: the first interpretation is that the microgranule is made of 62.5 to 91.5% sucrose, 0 to 37.5% of an additional component other than starch, and the remainder is starch; the second interpretation is that the microgranule is made up of 62.5 to 91.5% sucrose and 8.5 to 37.5% starch. Therefore, the metes and bounds of the claimed limitation are vague and indefinite and further clarification is requested. For the purposes of applying prior art, the examiner will apply either of the above interpretations accordingly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. The rejection of Claims 1, 3-16 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,489,026 (hereinafter Yalkowsky) in view of U.S. Patent No. 4,983,399 (hereinafter Maish) is hereby withdrawn by the examiner in view of the argument that neither Yalkowsky nor Maish teach the core to comprise 62.5-91.5% of sucrose and the remainder being starch.

2. Claims 1, 3-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,026,560 (hereinafter Makino et al.) in view of European Patent No. 0 361 874 (hereinafter Koyama et al.).

Applicant claims:

The Applicant claims a tablet comprising less than 40 mg/g of active principle attached as a coating to neutral microgranules comprising 62.5 to 91.5% sucrose and the remainder starch with a microgranule size of 200-400 μm, hardness of 0-20 daN, friability of 0-1%, and a disintegration time of less than 15 minutes. Claims 11 and 12 are drawn to a tablet premix comprising the active principle coated microgranules and 0-1% lubricant by mass. Claims 13 and 16 are drawn to a process for making the tablet by direct compression of the tablet premixes of Claims 11 or 12 at 5-50 kN or 10-30 kN, respectively.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Makino et al. teach spherical microgranules having a core made of Nonpareil (i.e. 75% sucrose and 25% corn starch) with a particle size of 14-80 mesh (i.e. 177-1410 μm), which is coated with a drug and low substituted hydroxypropylcellulose, L-HPC, mixture (i.e. the active principle is not coated with L-HPC, as excluded in claim 1 of the instant claims, but rather the drug is mixed with L-HPC) (column 3, lines 30-35; Examples 3 and 5; Experimental Example 1; and Claims 1-5, 10 and 13). Makino et al. further teach the combination ratio of the drug to the spraying powder is about 2-70 wt.% (column 3, lines 65-68), the ratio of binder to spraying powder is 1:1 or 1:1.2, which is then coated onto the Nonpareil core (column 3, lines 65-68; column 4, lines 5-6). Thus, the amount of drug present in the microgranules of Makino et al. is less than 1 wt.%, up to a maximum of about 35 wt.% depending on the thickness of the coating and the weight ratio of coating to Nonpareil.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Makino et al. do not teach a tablet formulation. However, it is well-known in the art at the time of the instant invention to either fill capsules with the microgranules, or compress the microgranules into a tablet for a suitable oral dosage formulation. For example, Koyama et al. teach microgranules comprising Nonpareil coated with an active drug and L-HPC, which are spherical and sieved to give uniform particle size of 12 to 32 mesh, which may be coated with a flavor masking agent or release controlling

agent (page 3, lines 50-58; and page 4, lines 1-4). Koyama et al. further teach the microgranules may be filled into capsules or mixed with other components to produce tablets (page 4, lines 4-6). Koyama et al. provide an example where the blended mixture of microgranules is compressed into tablets at a compression of 1 ton/cm^2 (i.e. 9.806 kN/cm^2), wherein the tablets have a disintegration time of 1.2 minutes (page 5, lines 40-56).

Also, Makino et al. do not teach the microgranules comprising less than about 1% of a lubricant. However, Koyama et al. teach about 0.7 wt.% magnesium stearate, a known lubricant, in the composition for tablet formation (page 5, lines 35-43).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to compress with a force of approximately 10 kN/cm^2 the microgranules of Makino et al., which comprise Nonpareil with a particle size of 14-80 mesh and are coated with a drug, into tablets as taught by Koyama et al., with an additional 0.7% lubricant as taught by Koyama et al. With regard to Claims 4 and 5, the hardness and friability of a tablet are inherent properties of the tablet that depend on the tablets composition and process of making. Therefore, since the tablets of the instant invention are comprised essentially of the same microgranules as Makino et al., and compressed under nearly the same pressure, the resulting hardness and friability would inherently be approximately the same.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

3. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. in view of Koyama et al as applied to Claims 7-9, 11-13 and 16 above, further in view of U.S. Patent No. 4,983,399 (hereinafter Maish).

Applicant claims:

The Applicant claims a tablet comprising less than 40 mg/g of active principle attached as a coating to neutral microgranules comprising 62.5 to 91.5% sucrose and the remainder starch with a microgranule size of 100-2000 µm, and about 0.25 wt.% lubricant.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Makino et al. and Koyama et al. are discussed above. In summary, Makino et al. teach spherical microgranules having a core made of Nonpareil coated with a drug and Koyama et al. teach forming tablets from Nonpareil cores coated with a drug and about 0.7 wt.% of a known lubricant, magnesium stearate.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Makino et al. and Koyama et al. do not teach the microgranules comprising on the order of 0.25 wt.% of a lubricant. However, Maish teaches lubricants are commonly used in tableting compositions because the lubricant promotes the fluidity of the compositions, to aid in the release of the tablets from the die in the manufacture of tablets and to promote uniform distribution of the active and inert components in the composition (column 3, lines 3-11). Maish further teaches the lubricant is typically in the range of about 0.25 to 5.0 wt.% of the total composition.(column 3, lines 48-52).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to formulate the compositions of Makino et al., which comprise Nonpareil with a particle size of 14-80 mesh and are coated with a drug, into tablets, as taught by Koyama et al., with an additional 0.25 to 5.0 wt.% lubricant as taught by Maish.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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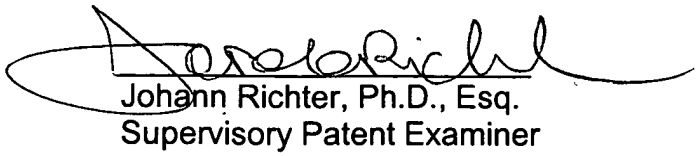

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